WHO Emergency Use Assessment Coronavirus disease (COVID-19) IVDs PUBLIC REPORT

Product: GLINE-2019-nCoV Ag (Self-Test)
Manufacturer: SHENZHEN YHLO BIOTECH CO., LTD.
EUL Number: EUL 0699-224-00
Outcome: Accepted

The EUL process is intended to expedite the availability of in vitro diagnostics needed in public health emergency situations and to assist interested UN procurement agencies and Member States in determining the acceptability of using specific products in the context of a Public Health Emergency of International Concern (PHEIC), based on an essential set of available quality, safety and performance data. The EUL procedure includes the following:

- Quality Management Systems Review and Plan for Post-Market Surveillance: desk-top review of the manufacturer's Quality Management System documentation and specific manufacturing documents;
- Product Dossier Review: assessment of the documentary evidence of safety and performance.

GLINE-2019-nCoV Ag (Self-Test), product codes G86256, G86257, G86278, G86279, G86280, and G86273, CE-mark regulatory version, manufactured by SHENZHEN YHLO BIOTECH CO., LTD, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, 518116 Shenzhen, China was listed on 11 July 2023.

Intended use:

According to the claim of intended use from SHENZHEN YHLO BIOTECH CO., LTD, *"GLINE-2019-nCoV Ag Test is a colloidal gold immunoassay (CGIA) for qualitative detection of SARS-CoV-2 nucleocapsid antigens in direct nasal swab from individuals who are suspected of SARS-CoV-2 within the first seven days of the onset of symptoms.*
Positive results indicate that viral antigens are present in the sample. Positive results do not exclude the possibility of bacterial infection or co-infection with other viruses.
Negative results do not exclude SARS-CoV-2 infection. SARS-CoV-2 infection or not should at least take into account your disease history, clinical signs, and symptoms consistent with COVID-19.
The GLINE-2019-nCoV Ag is intended for self-testing. Teenagers and children under 18 years old should follow the guidance from their guardians to perform a self-test. Elders above 80 should seek for assistance to perform a self-test."

Validated specimen type: Nasal swab specimens.

Test kit contents:

Component	1 test/kit (T/k) (G86256)	5T/kit (G86257)	7 T/kit (G86278)	10 T/kit (G86279)	15 T/kit (G86280)	20 T/kit (G86273)
Test Cassette (pcs)	1	5	7	10	15	20
Extraction Buffer, 400 µL/tube (pcs)	1	5	7	10	15	20
Sterile Swabs (pcs)	1	5	7	10	15	20
Biohazard Sample Bags (pcs)	1	5	7	10	15	20
Instruction For Use (pcs)	1	1	1	1	1	1

Materials required but not provided:
Timer

Storage
2-30°C.

Shelf-life upon manufacture:
18 months (real-time stability studies are ongoing).

Warnings/limitations:
Refer to the instructions for use (IFU).

Product dossier assessment

SHENZHEN YHLO BIOTECH CO., LTD submitted a product dossier for the GLINE-2019-nCoV Ag for detecting severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) antigen as per the "*Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting SARS-CoV-2 Nucleic Acid and rapid diagnostics tests detecting SARS-CoV-2 antigens (PQDx_0347)*". The information (data and documentation) submitted in the product dossier was reviewed by WHO staff and external technical experts (assessors) appointed by WHO.

Post listing Commitments for EUL:

As commitments to listing, SHENZHEN YHLO BIOTECH CO., LTD committed to:

1. Submit evidence of estimation of the product's Limit of Detection (LoD) with the WHO International Standard for SARS-CoV-2 antigen (NIBSC code: 21/368).

2. Submit simulated transport and ruggedness of packaging studies by July 2024.

The risk-benefit assessment is acceptable.

Quality Management Systems Review

To establish eligibility for WHO procurement, SHENZHEN YHLO BIOTECH CO., LTD was asked to provide up-to-date information about the status of their quality management system.

Based on the review of the submitted quality management system documentation by WHO staff, it was established that sufficient information was provided by SHENZHEN YHLO BIOTECH CO., LTD to fulfil the requirements described in the "*Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting SARS-CoV-2 Nucleic Acid and rapid diagnostics tests detecting SARS-CoV-2 antigens (PQDx_347)*".

The quality management documentation assessment is acceptable.

Plan for Post-Market Surveillance

Post-market surveillance, including monitoring all customer feedback, detecting and acting on adverse events, product problems, non-conforming goods and processes is a critical component of minimizing potential harm of an IVD listed for emergency use.

The following post-EUL activities are required to maintain the EUL listing status:
1. Notification to WHO of any planned changes to a EUL product, in accordance with "*WHO procedure for changes to a WHO prequalified in vitro diagnostic" (document number PQDx_121*); and
2. Post-market surveillance activities, in accordance with "*Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics"* (ISBN 978-92-4-001531-9).

SHENZHEN YHLO BIOTECH CO., LTD is also required to report all categories of complaints in a summarized form. There are certain categories of complaints and changes to the product that must be notified immediately to WHO, as per the above-mentioned documents.

The manufacturer has committed to ensuring that post-emergency use listing safety, quality, and performance monitoring activities are in place, per WHO guidance "*Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics*" (ISBN 978-92-4-001531-9).[1]

[1] Available on the web page https://www.who.int/publications/i/item/guidance-for-post-market-surveillance-and-market-surveillance-of-medical-devices-including-in-vitro-diagnostics

Scope and duration of procurement eligibility

GLINE-2019-nCoV Ag (Self-Test), product codes G86256, G86257, G86278, G86279, G86280, and G86273, manufactured by SHENZHEN YHLO BIOTECH CO., LTD, is considered to be eligible for WHO procurement for 12 months from the day of listing. The assay may be used for the detection of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) antigen. This listing does not infer that the product meets WHO prequalification requirements and does not mean that the product is listed as WHO-prequalified.

As part of the ongoing requirements for listing as eligible for WHO procurement, SHENZHEN YHLO BIOTECH CO., LTD must engage in post-market surveillance activities to ensure that the product continues to meet safety, quality and performance requirements. SHENZHEN YHLO BIOTECH CO., LTD is required to notify WHO of any complaints, including adverse events related to the use of the product, within 7 days and any changes to the product.

WHO reserves the right to rescind eligibility for WHO procurement if additional information on the safety, quality, and performance during post-market surveillance activities and if new data becomes available to WHO that changes the risk-benefit balance.

Labelling

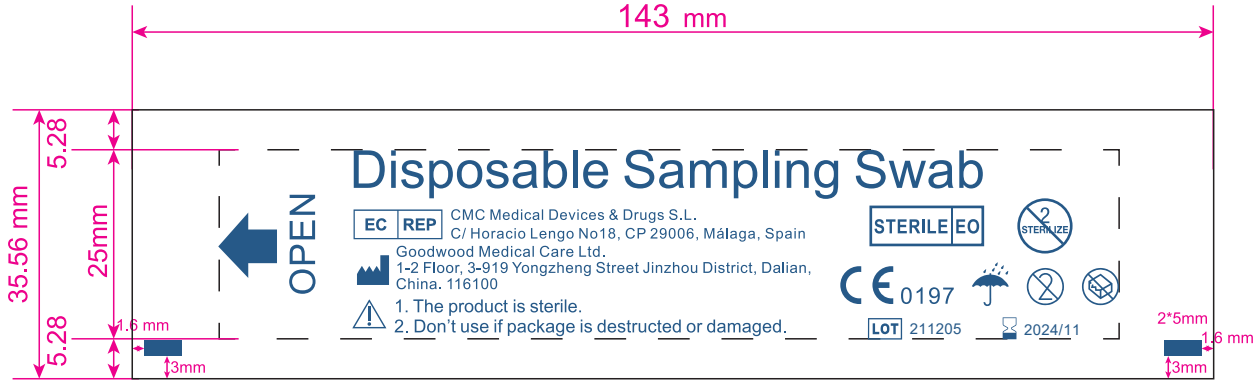
1.0 Labels

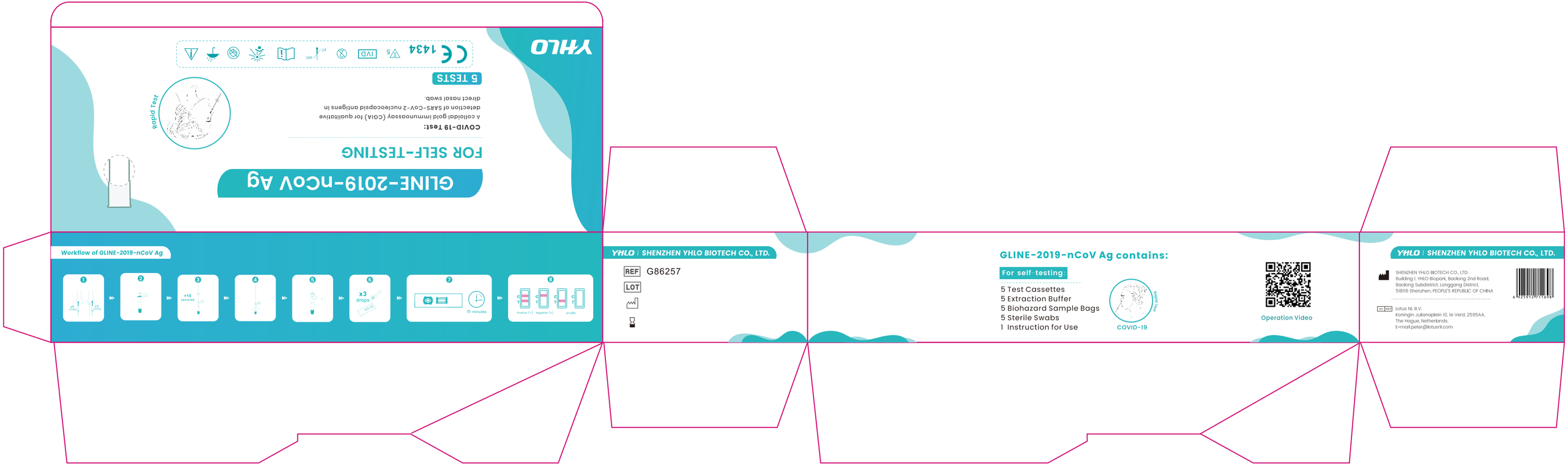
2.0 Instructions for Use (IFU)

1.0 Product labels

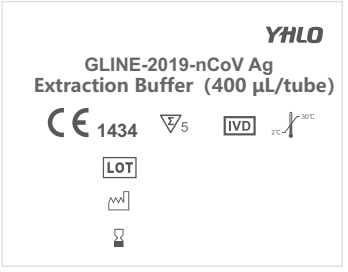
1.1 Outer box artwork and labels

Label for the box


143 mm
35.56 mm
5.28
25mm
5.28
1.6 mm
3mm
OPEN
Disposable Sampling Swab
EC REP
CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo No18, CP 29006, Málaga, Spain
Goodwood Medical Care Ltd.
1-2 Floor, 3-919 Yongzheng Street Jinzhou District, Dalian, China. 116100
1. The product is sterile.
2. Don't use if package is destructed or damaged.
STERILE EO
0197
LOT 211205
2024/11
2*5mm
1.6 mm
3mm

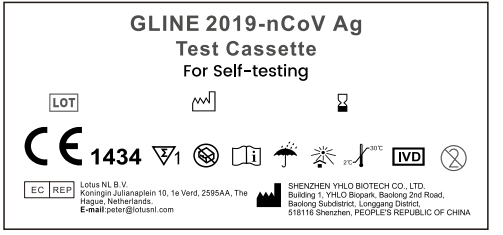


Label for box



Label for the extraction buffer

Label for the sterile swabs



Label for Test cassette foil pouch

YHLO

CE 1434 IVD

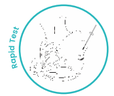
7 TESTS

GLINE-2019-nCoV Ag

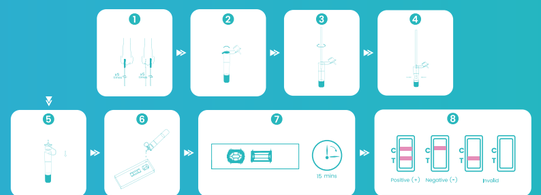
FOR SELF-TESTING

COVID-19 Test:

A colloidal gold immunoassay (CGIA) for qualitative detection of SARS-CoV-2 nucleocapsid antigens in direct nasal swab.



Workflow of GLINE-2019-nCoV Ag



YHLO | SHENZHEN YHLO BIOTECH CO., LTD.

REF G86278

LOT

GLINE-2019-nCoV Ag contains:

For self-testing:

7 Test Cassettes
7 Extraction Buffer
7 Biohazard Sample Bags
7 Sterile Swabs
1 Instruction for Use

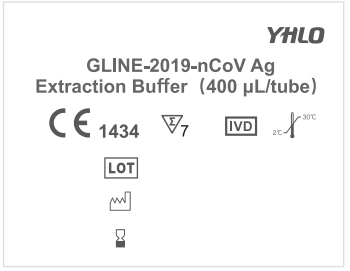
COVID-19

Operation Video

YHLO | SHENZHEN YHLO BIOTECH CO., LTD.

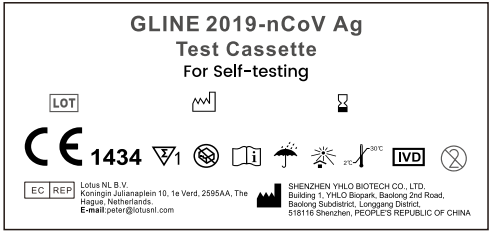
SHENZHEN YHLO BIOTECH CO., LTD.
Building 1, YHLO Biopark, Baolong 2nd Road,
Baolong Subdistrict, Longgang District,
518116 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

EC REP Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA,
The Hague, Netherlands.
E-mail:peter@lotusnl.com



Label for the extraction buffer

Label for the sterile swabs



Label for Test cassette foil pouch

YHLO

CE 1434 IVD

10 TESTS

Rapid Test

GLINE-2019-nCoV Ag

FOR SELF-TESTING

COVID-19 Test:
A colloidal gold immunoassay (CGIA) for qualitative detection of SARS-CoV-2 nucleocapsid antigens in direct nasal swab.

Workflow of GLINE-2019-nCoV Ag

YHLO | SHENZHEN YHLO BIOTECH CO., LTD.

REF G86279

LOT

GLINE-2019-nCoV Ag contains:

COVID-19

For self-testing:

10 Test Cassettes
10 Extraction Buffer
10 Biohazard Sample Bags
10 Sterile Swabs
1 Instruction for Use

Operation Video

YHLO | SHENZHEN YHLO BIOTECH CO., LTD.

SHENZHEN YHLO BIOTECH CO., LTD.
Building 1, YHLO Biopark, Baolong 2nd Road,
Baolong Subdistrict, Longgang District,
518116 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

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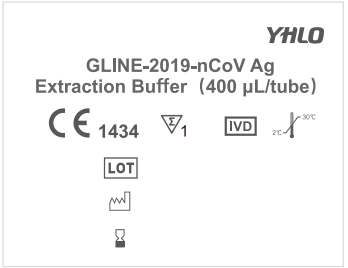
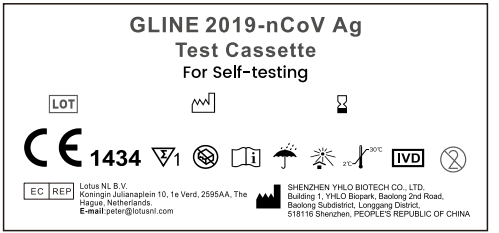
Koningin Julianaplein 10, 1e Verd, 2595AA,
The Hague, Netherlands.
E-mail:peter@lotusnl.com

6 942591 714132



Label for the extraction buffer

Label for the sterile swabs



Label for Test cassette foil pouch

YHLO

CE 1434 IVD

15TESTS

COVID-19 Test:

A colloidal gold immunoassay (CGIA) for qualitative detection of SARS-CoV-2 nucleocapsid antigens in direct nasal swab.

Rapid Test

GLINE-2019-nCoV Ag

FOR SELF-TESTING

Workflow of GLINE-2019-nCoV Ag

1 2 3 4 5 6 7 8

15 mins

Positive (+) Negative (-) Invalid

YHLO | SHENZHEN YHLO BIOTECH CO., LTD.

REF G86280

LOT

GLINE-2019-nCoV Ag contains:

Rapid Test

COVID-19

For self-testing:

15 Test Cassettes
15 Extraction Buffer
15 Biohazard Sample Bags
15 Sample Bags
1 Instruction for Use

Operation Video

YHLO | SHENZHEN YHLO BIOTECH CO., LTD.

SHENZHEN YHLO BIOTECH CO., LTD.
Building 1, YHLO Biopark, Baolong 2nd Road,
Baolong Subdistrict, Longgang District,
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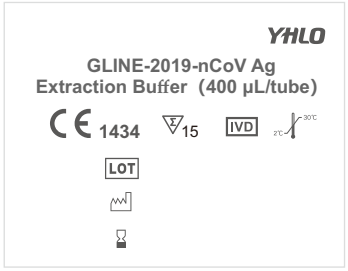
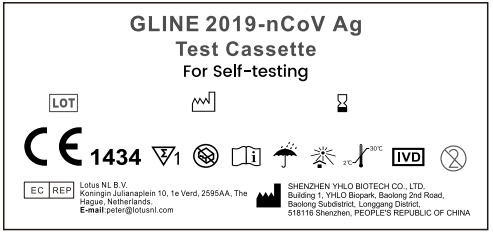
E-mail:peter@lotusnl.com

6 09259127141149



Label for the extraction buffer

Label for the sterile swabs



Label for Test cassette foil pouch

YHLO

GLINE-2019-nCoV Ag

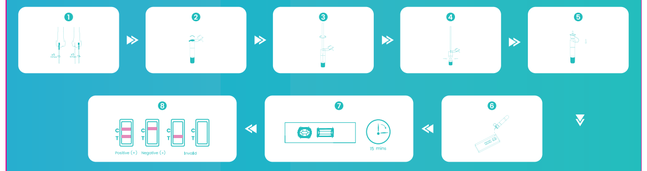
FOR SELF-TESTING

COVID-19 Test:
A colloidal gold immunoassay (CGIA) for qualitative detection of SARS-COV-2 nucleocapsid antigens in direct nasal swab.

20 TESTS

CE 1434 20 IVD

Workflow of GLINE-2019-nCoV Ag



SHENZHEN YHLO BIOTECH CO., LTD.
Building 1, YHLO Biopark, Baokang 2nd Road,
Baokang Subdistrict, Longgang District,
518116 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

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The Hague, Netherlands.
E-mail:peter@lotusnl.com

GLINE-2019-nCoV Ag
contains:

EN For Self-testing

20 Test Cassettes
20 Extraction Buffer
20 Biohazard Sample Bags
20 Sterile Swabs
1 Instruction for Use

Operation Video

YHLO

GLINE-2019-nCoV Ag

FOR SELF-TESTING

COVID-19 Test:
A colloidal gold immunoassay (CGIA) for qualitative detection of SARS-COV-2 nucleocapsid antigens in direct nasal swab.

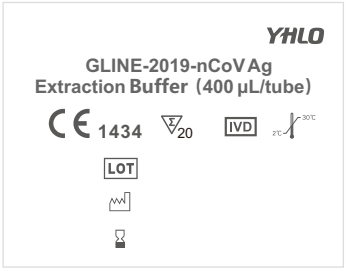
20 TESTS

CE 1434 20 IVD

YHLO | SHENZHEN YHLO BIOTECH CO., LTD.

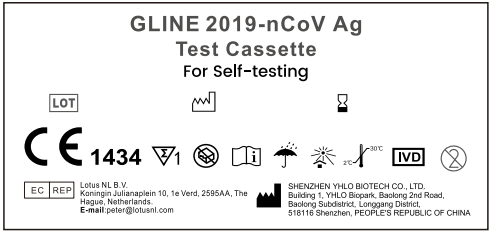
REF G86273

LOT



Label for the extraction buffer

Label for the sterile swabs



Label for Test cassette foil pouch

2.0 Instructions for use[2]

[2] English version of the IFU was assessed by WHO. It is the responsibility of the manufacturer to ensure correct translation into other languages.

ENGLISH

CE 1434 For self-testing

IVD *In vitro* diagnostic medical device

INTENDED USE

The GLINE-2019-nCoV Ag Test is a colloidal gold immunoassay (CGIA) for qualitative detection of SARS-CoV-2 nucleocapsid antigens in direct nasal swab from individuals who are suspected of SARS-CoV-2 within the first seven days of the onset of symptoms.
Positive results indicate that viral antigens are present in the sample. Positive results do not exclude the possibility of bacterial infection or co-infection with other viruses.
Negative results do not exclude SARS-CoV-2 infection. SARS-CoV-2 infection or not should at least take into account your disease history clinical signs and symptoms consistent with COVID-19.
The GLINE-2019-nCoV Ag is intended for self-testing. Teenagers and children under 18 years old should follow the guidance from their guardians to perform a self-test. Elders above 80 should seek for assistance to perform a self-test.

SUMMARY AND EXPLANATION

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease.
People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days but still remains infectious during this period. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

PRINCIPLE OF THE TEST

The GLINE-2019-nCoV Ag Test employs colloidal gold immunoassay technology in a sandwich design to detect the SARS-CoV-2 nucleocapsid protein.

- When specimens are processed and added into sample well, the specimen will flow along the test strip by capillary action. If the SARS-CoV-2 nucleocapsid protein exists in the specimen, the protein will combine with colloidal gold labeled SARS-CoV-2 antibodies. This immune complex will be captured by immobilized anti-SARS-CoV-2 antibodies in the detection region (T) and form a coloured detection line, which means SARS-CoV-2 antigen positive.
- The detection cassette also includes a control region(C) . Upon completion of a valid test, a coloured control line should appear regardless of whether the SARS-CoV-2 antigen is present in the sample. If the control line does not appear, the test result is invalid and the sample should be retested with another test cassette.

KIT COMPONENTS

GLINE-2019-nCoV Ag contains:

REF / Components	G86256	G86257	G86278	G86279	G86280	G86273
Test Cassette (pcs)	1	5	7	10	15	20
Extraction Buffer, 400 μL/tube (pcs)	1	5	7	10	15	20
Sterile Swabs (pcs)	1	5	7	10	15	20
Biohazard Sample Bags (pcs)	1	5	7	10	15	20
Instruction For Use (pcs)	1	1	1	1	1	1

MATERIALS REQUIRED (BUT NOT PROVIDED)

- Timer.

WARNINGS AND PRECAUTIONS

IVD For in vitro diagnostic use only.

- Read instructions prior to performing the test. Follow all instructions to achieve accurate results.
- Use immediately after opening the pouch containing the test cassette.
- Avoid touching any bleeding areas of the nostril area during specimens collection, as excess blood or mucus on the swab may interfere with the test and yield a false result.
- Each single Test Cassette, Sterile Swab, Extraction Buffer and Biohazard Sample Bag are single use. Do not reuse individual components.
- Do not dip the Sterile Swab into buffer or other liquid before inserting the Swab into the nose.

- The provided Sterile Swab should be used only for nasal specimen collection.
- Do not use if the package of test device is damaged.
- Do not use if the package of sterile swabs is damaged.
- Do not use the kit contents beyond the expiration date.
- Do not eat, drink, or smoke in the area where the specimens and kit contents are handled.
- Do not interchange kit contents from different lots.
- Do not make any medical decision without first consulting your medical practitioner.
- Clean and disinfect all spills of specimens or buffer using appropriate disinfectant, eg. 75% alcohol.
- Please take the necessary safety measures (e.g. face mask, gloves) when testing for other people.
- If the extraction buffer makes contact with the skin or eye, wash/ flush with a large volume of water.If skin irritation, rash or other abnormal reaction occurs, please get medical advice/attention.
- Children and elders please use the test under the guardian assistance.
- Keep the test kit out of reach of children.
- Direct swab specimen should be tested immediately after collection.
- To prevent contamination, only touch the sides of the Test Device and ensure the Swab end only touches the nasal cavity and inside of Buffer Tube
- If the test has been stored in a refrigerator, allow the test to equilibrate to room temperature (20-30°C) for 30 minutes before use.
- If the test does not work or its performance changes, please repeat test procedure with a new test kit or contact manufacturer.

LIMITATIONS

- The accuracy of the test relies on the whole testing procedure being performed correctly. Failure to follow the instructions will adversely affect test accuracy. Retesting is recommended to confirm the results if the test results are inconsistent with clinical symptoms.
- This product is only used for qualitative detection of SARS-CoV-2 antigens in human nasal swab specimens and cannot quantitatively detect antigen concentration in samples.
- A confirmed diagnosis should only be made by a health care professional after all clinical and laboratory findings have been evaluated.
- Negative results in cases where COVID-19 disease is suspected should be reviewed by a confirmatory test if necessary.
- False negative results are more likely to occur if the test is not performed within the first 7 days of symptom onset.
- The tests are less reliable in the later phase of infection and in asymptomatic individuals.
- There is a higher chance of false-negative results with Ag RDT self-tests than with laboratory-based nucleic acid test.
- Repeat testing (e.g. 1-3 days) is recommended if there is an ongoing suspicion of infection, being in a high risk setting or where there is an occupational risk or other requirements.
- The negative results may not mean a person is not infectious and if symptoms continue, You are also advised to continue following local guidelines for self-isolation and consult your doctor.
- A negative result does not rule out infection with another respiratory pathogen.
- Improper collection, handling, transport of samples, or low virus in samples may also cause false negative results.
- Reading the test results earlier than 15 minutes or later than 20 minutes may give incorrect results.
- The results may be affected if the test is used in enviroments with humidity greater than 75%.

STORAGE AND STABILITY

- The product should be stored at 2-30°C, dry and out of light, it is validity for 18 months.
- Each test cassette should be used immediately after opening the sealed foil pouch. The test should be used in a room temperature (20-30°C) environment.

FREQUENTLY ASKED QUESTIONS

What are the symptoms of COVID-19?

The most common symptoms of COVID-19 are: fever, dry cough and fatigue. Other less common symptoms that may affect some patients include: loss of taste or smell, nasal congestion,conjunctivitis (also known as red eyes), sore throat, headache,muscle or joint pain,different types of skin rash,nausea or vomiting,diarrhea,chills or dizziness. People of all ages who experience fever and/or cough associated with difficulty breathing or shortness of breath, chest pain or pressure, or loss of speech or movement should seek medical care immediately. If possible, call your health care provider, hotline or health facility first, so you can be directed to the right clinic.

When should I get a test for COVID-19?

Anyone with symptoms should be tested, wherever possible. People who do not have symptoms but have had close contact with someone who is, or may be, infected may also consider testing - contact your local health guidelines and follow their guidance.

What should I do if I get a negative test result?

A negative test result means that proteins from the virus that causes COVID-19 was not detected. You might not have COVID-19. However, a negative result does not rule out the risk of COVID-19 infection. This means you possibly still have COVID-19 even though the test result is negative. If you continue to experience COVID-19 like symptoms such as headaches, migraines, fever, loss of smell or taste, contact your doctor or health department for advice on whether a PCR test is required. In addition, you can repeated the test with a new test kit. In case of suspicion, you could repeat the test after 1-2days because can't be precisely detected in all phases of infection.

What should I do if I get a positive test result?

A positive test result means that proteins from the virus that causes COVID-19 was detected. It is likely that you will need to perform self-isolation at home to prevent the spread of COVID-19. A positive result does not rule out coinfection with other pathogens. Please follow local guidelines for self-isolation and immediately contact your doctor or local health department.

What should I do if I get an invalid test result?

You might not correctly perform the test. You should read the instructions again and repeat the procedure with a new test kit or contact manufacturer.

How accurate is the GLINE-2019-nCoV Ag?

The GLINE-2019-nCoV Ag test has been shown in a clinical study involving 653 direct nasal swabs, performed by 2 locations and tested immediately after collection, to correctly identify 99.30% (424 out of 427) of SARS-CoV-2 negative nasal samples (known as test specificity). The test correctly identified 90.27% (204 out of 226) SARS-CoV-2 positive nasal samples (known as test sensitivity). Results from the GLINE-2019-nCoV Ag test were compared with a reference RT-PCR assay.

REFERENCES

- Zhou P, Yang XL, Wang XG, et al. A pneumonia outbreak associated with a new coronavirus of probable bat origin[J]. Nature, 2020.
- Lu R, Zhao X, Li J, et al. Genomic characterisation and epidemiology of 2019 novel coronavirus: implications for virus origins and receptor binding[J]. Lancet, 2020.

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ANNEX A: Explanation of abbreviation

Abbreviation	Explanation
REF	Catalogue number
Σ	Contains suf cient for <n> tests
	Manufacturer
EC REP	Authorized representative in the European Community
	Caution
	Consult instructions for use
IVD	*In vitro* diagnostic medical device
LOT	Batch code
	Date of manufacture
	Use-by date
2℃ 30℃	Temperature limit (2-30 ˚C)
	This way up
	Do not re-use
	Do not use if package is damaged
	Keep dry
	Keep away from sunlight
CE 1434	CE Conformity Marking

INSTRUCTIONS FOR USE

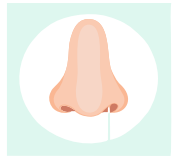
Please scan the QR code to watch the video of instructions before testing.

TEST PROCEDURE

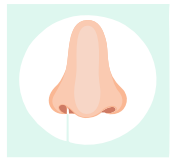
Step 1:
Wash or disinfect your hands. Ensure they are dry before testing.

Step 2:
Ensure the completeness of components and check the expiration date on the box. Do not use if the component is damaged or if the kit is expired.

Step 3:
Take out the sterile swab from package. Do not touch the soft end of swab.



Step 4:
Carefully insert the soft end of swab into at about 1.5 cm of your nostril and gently rotate the swab at least 5 times.



Step 5:
Slowly remove the swab from your nostril. Using the same swab, repeat step 5 in your other nostril.

Step 6:
Peel off the foil film of extraction buffer tube. Set the tube on the stand hole of the package box.

Step 7:
Insert the soft end of swab into the bottom of extraction buffer tube.

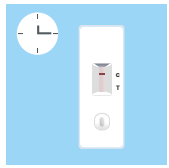
Step 8:
Squeeze the tube around the soft end of swab up and down in the fluid at least 15 seconds.

Step 9:
Remove the swab while squeezing the sides of the tube to release the liquid from the swab.

Step 10:
Immediately place theprocessed swab in the biohazard sample bag to avoid virus spreading. The swab may contain infectious material and infecting other person.

Step 11:
Press the included cap tightly onto the extraction buffer tube. Mix the fluid thoroughly by swirling or flicking the bottom of the tube.

Step 12:
Place the test cassette on a well-lit, flat surface. Invert the extraction buffer tube and hold it vertically. Gently squeeze the body of tube, adding **3 drops of liquid into the sample well. DO NOT add more than 3 drops. Start the timer immediately after adding the extracted specimen to the specimen well of the test cassette.**



Step 13:
Read the results15-20 minutes afteradding liquid to thesample well. Results read before 15 minutes or after 20 minutes may be invalid.

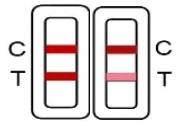
⚠ **IMPORTANT: Do not move or lift the test cassette when reading the result.**

Step 14:
After reading test result, place all components of the test device in the biohazard sample bag and dispose of it according to local regulation. Do not reuse any used components.

READ TEST RESULTS

Positive

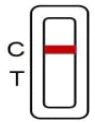
Both Control (C) line and Test (T) line are present. Line intensities may vary from faint to strong intensity. A faint test line is also considered as a positive result.



It's very likely you have COVID-19. You should follow local guidelines for self-isolation and immediately contact your doctor or local health department.

Negative

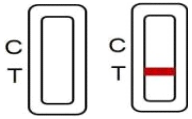
The Control (C) line is present and no Test (T) line is present.



This indicates virus causing COVID-19 is not detected. You are unlikely to have COVID-19. If the viral load is too low ($<2\times10^2$ $TCID_{50}$/mL) or too high ($1.6\times10^5$$TCID_{50}$/mL), it will also lead to false-negative result. A negative result does not rule out the risk of COVID-19 infection. Please take personal protection following the local guideline and constantly monitor self healthy condition.

Invalid

No Control (C) line is present.



The test does not work.You should read the instructions again and repeat the procedure with a new test kit or contact manufacturer.

DISPOSAL

After reading test result, place all components of the test device in the biohazard sample bag and dispose of it according to local regulation. Do not reuse any used components.